



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,641	09/23/2005	Prasun K. Chakravarty	21230YP	1919
210 7590 06/16/2008 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907				
EXAMINER LEESER, ERICH A				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
06/16/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/550,641

**Applicant(s)**

CHAKRAVARTY ET AL.

**Examiner**

Erich A. Leeser

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 32, 41, 42 and 46-58 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33, 38 and 43 is/are allowed.
- 6) ☒ Claim(s) 1-2, 7, 12, 14, 19, 24, 29, 37 and 44-45 is/are rejected.
- 7) ☒ Claim(s) 3-6, 8-11, 13, 15-18, 20-23, 25-28, 30, 31, 34-36, 39 and 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3-3-06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restriction***

In correspondence dated October 11, 2007, Applicant elected with traverse Group I drawn to compounds and compositions of formula I or II wherein either HET-1 or HET-2 (or both) is/are 1,3-diazine.

Applicant argues that the groups are related because a "reasonable number of species of the invention can be claimed if there is an allowable generic claim in the application" and that "there is no additional burden on the part of the Examiner to conduct the prior art search for examination of the present application in total."

Examiner does not find this argument persuasive because the four groups of the restriction requirement all possess different classification and as such significant search burden would exist absent the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-31, 33-40 and 43-45 are examined. Claims 32, 41-42 and 46-58, the remaining subject matter being drawn to the non-elected invention, are withdrawn per 37 CFR 1.142(b).

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Oath and Declaration***

Examiner has marked item 11 in the Office Action Summary page because it appears as though the Office has received signatures from all of the named inventors except Michael H. Fisher.

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

***Information Disclosure Statement***

The references contained in the IDS dated March 3, 2006, are made of record.

***Priority***

Acknowledgement is made that this application is a 371 of PCT/US04/08532, filed on March 19, 2004, which claims benefit of 60/456,312, filed on March 24, 2003.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) In claim 1, the figure for a compound of Formula (II) depicts "R<sub>1</sub>" whereas the text of the variable group definitions says "R<sup>1</sup>". The same issue is present with R<sub>2</sub> and R<sub>7</sub>. Correction and consistency are required.
- ii) Also in claim 1, the definition of HET-2 is unclear because one of ordinary skill in the art would not necessarily be able to figure out which squiggly line represents the HET-1 side of the

Art Unit: 1624

molecule and which squiggly line represents the phenyl side of the molecule. Clarification is required.

iii) In claim 37, the figure depicts "R<sup>1</sup>" whereas the table below indicates "R<sup>2</sup>". Correction and consistency are required.

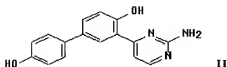
### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1, 2, 7 and 44-45 are rejected under 35 USC 102(a) as being anticipated by Cao, et al., WO 02/096867. Cao, et al. teaches pyrimidinyl compounds, which include instant compounds. For example, the compound



of the reference anticipates the aforementioned claims where R<sup>1</sup> is NR<sup>a</sup>R<sup>b</sup>, R<sup>a</sup> and R<sup>b</sup> are both hydrogen, R<sup>2</sup> and R<sup>3</sup> are both hydrogen, R<sup>4</sup> or R<sup>5</sup> is hydroxy and the other is hydrogen, one of R<sup>6</sup>, R<sup>7</sup>, or R<sup>8</sup> is -OR<sup>a</sup> and the other two are hydrogen, and R<sup>a</sup> is also hydrogen. Therefore, the instant claims 1, 2, 7 and 44-45 are anticipated by Cao, et al., WO 02/096867.

### ***Claim Rejections 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 14, 19, 29, and 44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Katoh, et al., U.S. Patent No. 4,783,466.

Katoh, et al. teaches structurally similar pyrimidinyl compounds (see column 1, line 25 to column 6, line 23; compounds of formulae I-II, V, VI, VIII, and X and R groups).

Whereas Examiner could not find overlap between the Examples of the reference and Applicant's claimed exemplified compounds, the compounds disclosed by the reference generically embrace the instant compounds when the variable R groups are at least hydrogen, HET-1 is the sixth of the eight configurations, and HET-2 is the sixth of the eight configurations.

One of ordinary skill in the art would be motivated to modify the compounds of Katoh, et al. with other substituents to arrive at the instant pyrimidinyl compounds even though Katoh, et al. used their compounds as a plant disease protectant instead of the instant use as sodium channel blockers for the treatment of CNS disorders.

As such, the instant claims 1, 14, 19, 29, and 44 are obvious in view of Katoh, et al., U.S. Patent No. 4,783,466.

Claims 1, 12, 19, 24, and 44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Katoh, et al., U.S. Patent No. 4,873,248.

Katoh, et al. teaches structurally similar pyrimidinyl compounds (see column 1, line 25 to column 5, line 27; compounds of formulae I-IV, VI and VIII and R groups).

Whereas Examiner could not find overlap between the Examples of the reference and Applicant's claimed exemplified compounds, the compounds disclosed by the reference generically embrace the instant compounds when the variable R groups are at least hydrogen, HET-1 is the first of the eight configurations, and HET-2 is either the fourth or the eighth configuration (see indefiniteness issue ii) above).

One of ordinary skill in the art would be motivated to modify the compounds of Katoh, et al. with other substituents to arrive at the instant pyrimidinyl compounds even though Katoh, et al. used their compounds as a fungicide instead of the instant use as sodium channel blockers for the treatment of CNS disorders.

As such, the instant claims 1, 12, 19, 24, and 44 are obvious in view of Katoh, et al., U.S. Patent No. 4,873,248.

#### ***Claim Objections***

Claims 3-6, 8-11, 13, 15-18, 20-23, 25-28, 30-31, 34-36 and 39-40 are objected to as being dependent upon rejected independent claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

#### ***Allowable Subject Matter***

Claims 33, 38, and 43 are patentable. The closest prior art appears to be Gallant, et al., WO 01/81312. The Gallant et al. reference teaches phenyl and biaryl derivative compounds,

including compound 5 found on page 18 of the reference which differs from the instant compounds in that it has chlorine at the corresponding position of instant R1 which does not teach halogen. Therefore, the claims are seen to be free of prior art.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

**Erich A. Leeser**  
*Patent Examiner*, Art Unit 1624  
United States Patent and Trademark Office  
400 Dulany Street, Remsen 5C11  
Alexandria, VA 22314-5774  
Tel. No.: (571) 272-9932

/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624  
**James O. Wilson**  
*Supervisory Patent Examiner*, Art Unit 1624  
United States Patent and Trademark Office  
400 Dulany Street, Remsen 5A11  
Alexandria, VA 22314-5774  
Tel. No.: (571) 272-0661